REMARKS

Claims 1-47 are pending in this application. Claims 9, 17-21, 23, 33, 34 and 44 are under consideration and were rejected in the current Office action. Claims 1-8, 10-16, 22, 24-32, 35-43, and 45-47 are currently withdrawn from consideration. As reflected in the listing of claims submitted herewith, claim 9 is currently amended, without prejudice, for clarification purposes. Support for the amendment can be found throughout the specification, for example, at page 6, line 19 to page 7, line 12; at page 13, line 28 to page 14, line 8; at page 16, lines 1-2; and in Examples 2 and 3, pages 24-27. Applicants submit that no new matter is being added by this Amendment and Response.

Rejection under 35 U.S.C. §112, first paragraph

Claims 9, 17-21, 23, 33, 34 and 44 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office action states that "the specification does not provide guidance on how to distinguish between age or osteoarthritis or rheumatoid arthritis or gout or FMS or PMR", and that the specification doesn't provide guidance for using OP-1 levels to positively determine an age-related tissue disorder.

Independent claim 9 is directed toward a method for determining the presence of an age-related tissue disorder in a patient by comparing an amount of OP-1 protein present in a patient sample with a predetermined standard amount. Claim 9 is currently amended to clarify that the predetermined standard amount is an amount measured in a sample known to not have an age-related tissue disorder present, and that a decrease in the amount of OP-1 protein present in the patient sample compared to the amount in the predetermined standard is indicative of the presence of the age related disorder in the patient. Claims 17-21, 23, 33, 34, and 44 depend directly from independent claim 9.

Claim 9, as amended and as originally filed, is fully enabled by the specification. For example, on page 13, line 28 to page 14, line 6, the specification discusses how the levels of OP-1 protein in a patient can be compared to a predetermined standard control level of OP-1 that corresponds to a particular disease, stage of disease, severity of disease or the particular tissue grade to determine whether the patient has that disease, stage of disease, severity or tissue grade. The specification also provides that OP-1 levels in a patient may be compared with levels in that

patient that were determined before the onset of disease or during remission of the disease. Furthermore, Examples 2 and 3 describe experiments in which these comparisons were made to determine whether there is a difference in the level of OP-1 protein in normal donors compared to the level of OP-1 protein in patients with an age-related disorder, i.e., osteoarthritis. Example 3 demonstrates a difference in the OP-1 levels measured in normal newborn and normal adult donors having no documented history of joint disorder compared to the OP-1 levels measured in patients who have been diagnosed with osteoarthritis.

The Office action also states that it is unclear what is considered to be an age-related tissue disorder as recited in the claims. The specification does, however, describe what is considered to be an age-related tissue disorder. At least on page 7, lines 1-3 and page 16, lines 1-2, the specification provides that age-related disorders, such as disorders characterized by abnormal tissue aging, include, for example, osteoarthritis and osteoporosis.

As demonstrated above, the claims and the specification do in fact meet the requirements of §112, first paragraph. The specification provides guidance on how to practice the method of claim 9 to determine the presence of, in particular, an age-related disease which includes, for example, osteoarthritis and osteoporosis, by detecting whether there is a decrease in the amount of OP-1 in a patient compared to the amount of OP-1 in a known standard. Accordingly, independent claim 9 is enabled by the specification as originally filed. Thus, Applicants respectfully request reconsideration of this rejection and submit that independent claim 9, as well as dependent claims 17-21, 23, 33, 34, and 44, are in condition for allowance.

Rejection under 35 U.S.C. §112, second paragraph

Claims 9, 17-21, 23, 33, 34 and 44 are rejected under 35 U.S.C. §112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Office action states that it is unclear what is considered to be an age-related tissue disorder. As demonstrated above, the specification clearly describes what is considered to be an age-related tissue disorder in that, at least on page 7, lines 1-3 and page 16, lines 1-2, the specification provides that age-related tissue disorders include disorders characterized by abnormal tissue aging, such as, for example, osteoarthritis and osteoporosis.

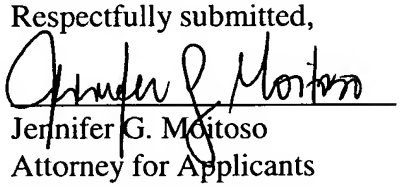
The Office action also states that is it unclear what difference the applicant is referring to with regard to the recitation of "a difference in the amount of OP-1 protein." Independent claim 9 is amended to clarify that a decrease in the amount of OP-1 protein present in the patient sample compared to the amount of OP-1 in the predetermined standard indicates the presence of an age-related tissue disorder in the patient.

Accordingly, Applicants submit that independent claim 9, as well as claims 17-21, 23, 33, 34 and 44 which depend there from, particularly point out and distinctly claim the subject matter of the invention. Thus, Applicants respectfully request reconsideration of this rejection and submit that claims 9, 17-21, 23, 33, 34 and 44 are in condition for allowance.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that claims 9, 17-21, 23, 33, 34 and 44 are in condition for allowance, and request early and favorable action. If the Examiner believes that a telephonic interview would be helpful, the Examiner is invited to contact the undersigned attorney.

Respectfully submitted,



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